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510(k) SUMMARY

Single Use Electrosurgical Knife Series

OCT 30 2009

1 General Information

- Applicant:

OLYMPUS MEDICAL SYSTEMS CORP.
2951 Ishikawa-cho, Hachioji-shi, Tokyo, Japan 192-8507
Establishment Registration No: 8010047

- Official Correspondent:

Stacy Abbatiello Kluesner, M.S., RAC
Regulatory Affairs & Quality Assurance
Olympus America Inc.
3500 Corporate Parkway
PO Box 610
Center Valley, PA 18034-0610
Phone: 484-896-5405
FAX: 484-896-7128
Email: Stacy.Kluesner@olympus.com
Establishment Registration No: 2429304

- Manufacturer:

Aomori Olympus
248-1 Okkonoki 2-chome Kuroishi-shi,
Aomori, Japan, 036-0367
Establishment Registration Number: 9614641

2 Device Identification

- Device Trade Name: Single Use Electrosurgical Knife Series
- Common Name: Electrosurgical Knife
- Regulation Number: 21 CFR 876.4300
- Regulation Name: Endoscopic electrosurgical unit and accessories
- Regulatory Class: II
- Classification Panel: Gastroenterology and urology
- Product Code: KGE

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3 Predicate Device Information

Device Name	Common Name	510(k) No.	Manufacturer
KD-1L-1	Electrosurgical Knife	Preamendment Device	Olympus Medical Systems Corp.

4 Device Description

The following five models of Single Use Electrosurgical Knives are the subject of this 510(k) notification: KD-610L, KD-611L, KD-620LR, KD-630L and KD-640L.

The KD-610L and KD-611L knives have isolation tips on the distal tip to prevent inadvertent deep cauterization. The KD-611L knive also has an electrode at the bottom of the isolation tip, which can also cut tissue.

The KD-620LR knive is a L-shaped knife, which cutstissue by hooking the mucous membrane. This device is rotatable so that both longitudinal and lateral dissection is possible.

The KD-630L knife consists of flexible wire, which is adjustable by the user, preventing inadvertent deep cauterization.

The KD-640L knife has a triangle tip to the distal end of the knife, which hooks mucous membrane to cut. Both longitudinal and lateral dissection is possible without rotating the instrument due to the triangle tip design.

5 Indications for Use

Single Use Electrosurgical Knife KD-610L/KD-611L/KD-620LR/KD-630L/KD-640L
This instrument has been designed to be used with Olympus endoscopes and electrosurgical units to cut tissue within the digestive tract and using high-frequency current.

6 Comparison of Technological Characteristics

The Single Use Electrosurgical knives are basically identical to the predicate device in intended use, and similar in specifications except for cutting knife shapes.

7 Conclusion

When compared to the predicate device, the Single Use Electrosurgical Knives do not incorporate any significant changes that could affect the safety or effectiveness of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

OLYMPUS MEDICAL SYSTEMS CORP.
% Ms. Abbatiello Kluesner, M.S., RAC
Regulatory Affairs & Quality Assurance
Olympus America, Inc.
3500 Corporate Parkway
PO Box 610
CENTER VALLEY PA 18034-0610

OCT 30 2009

Re: K092309
Trade/Device Name: Single Use Electrosurgical Knife Series
Regulation Number: 21 CFR 876.4300
Regulation Name: Endoscopic electrosurgical unit and accessories
Regulatory Class: II
Product Code: KNS
Dated: July 30, 2009
Received: August 3, 2009

Dear Ms. Kluesner:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K092309

Device Name: Single Use Electrosurgical Knife series

Indications For Use:

Single Use Electrosurgical Knife KD-610L/KD-611L/KD-620LR/KD-630L/KD-640L

This instrument has been designed to be used with Olympus endoscopes and electrosurgical units to cut tissue within the digestive tract using high-frequency current.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K092309